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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/717,760

11/20/2003

Sachiko Kuno

9694-000006

8794

27572 7590 09/26/2008  
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EXAMINER

CARTER, CANDICE D

ART UNIT

PAPER NUMBER

3629

MAIL DATE

DELIVERY MODE

09/26/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/717,760	<b>Applicant(s)</b> KUNO, SACHIKO	
	<b>Examiner</b> CANDICE D. CARTER	<b>Art Unit</b> 3629	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11 June 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/20/2003</u> .  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. This communication is a First Action Non-Final on the merits. Claims 1-7, as originally filed, are currently pending and have been considered below.

#### ***Election/Restrictions***

The inventions are distinct, each from the other because of the following reasons:

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-7, drawn to a method of doing business among two or more entities engaged in research and development, wherein the object of said research and development is the subject of a multinational portfolio, classified in class 705, subclass 1.
- II. Claims 8-11, drawn to a computer implemented method of providing a secondary market for regulatory data and information among two or more entities engaged in research and development where the research and development is the subject of a multinational patent portfolio, classified in class 705, subclass 1.
- III. Claims 12-22, drawn to a method for allowing mutual access of regulatory approving data required for obtaining an approval of a government and/or regulations among a plurality of parties resident in a variety of jurisdictions, classified in class 705, subclass 1.

3. Inventions I and II are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct if they do not overlap in scope and are not obvious variants, and if it is shown that at least one subcombination

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is separately usable. In the instant case, subcombination II has separate utility such as calculating and recording values related to a territorial distribution. See MPEP § 806.05(d).

The examiner has required restriction between subcombinations usable together. Where applicant elects a subcombination and claims thereto are subsequently found allowable, any claim(s) depending from or otherwise requiring all the limitations of the allowable subcombination will be examined for patentability in accordance with 37 CFR 1.104. See MPEP § 821.04(a). Applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

4. Inventions I and III are directed to related processes. The related inventions are distinct if: (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed have materially different functions. Invention I is directed towards engaging in research between two or more entities and Invention II is directed towards obtaining an approval of a government and/or regulations. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

5. Applicant's election without traverse of Group I (claims 1-7) in the reply filed on June 11, 2008 is acknowledged.

***Claim Rejections - 35 USC § 101***

6. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. **Claims 1-7 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.**

Claims 1-7 are directed to a method of doing business among two or more entities engaged in research and development.

Examiner contends that a process must be (1) tied to another statutory class (such as a particular apparatus) or (2) transform underlying subject matter (such as an article or materials) to a different state or thing. Neither of these requirements is met by these claims, therefore, these claims do not qualify as a statutory process. In the instant case, the method recited is not tied to an apparatus and, thus, is not believed to fall within a statutory category.

***Claim Rejections - 35 USC § 112***

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. **Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

Claim 1 recites the limitation “providing a secondary market for regulatory data and information obtained in one party’s research and development whereby it can be utilized by another party in its territory”.

It is unclear what Applicant means by the limitation in this claim. Applicant has not mentioned a primary market; Examiner is unsure what the secondary market is secondary to. Also, it is unclear what is being utilized by another. Is it the regulatory data and information or the research and development that are being used by the other party? Appropriate clarification is requested.

Claim 2 recites the limitation “may exceed a first party’s cost of development”.

The term “may” is indefinite because Applicant is not positively claiming the limitations after the use of the term. It is unclear if Applicant claims that compensation is to exceed the cost of development or just have the ability or option to exceed the cost of development. Appropriate clarification is requested.

### ***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**11. Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nutter et al. (2003/0061133, hereinafter Nutter) in view of PR Newswire (2001).**

As per claim 1, Nutter discloses “A method of doing business among two or more entities engaged in research and development, wherein the object of said

research and development is the subject of a multinational patent portfolio, said method comprising:

a) providing a territorial distribution of at least some of the rights under said patent portfolio (§ 19 and 20 discloses a selling entity having an IP asset that is a portfolio of patents and selling it to an investment entity and § 23 discloses the IP investment entity licensing out the right to use the IP in a defined geographic territory)

Nutter, however, fails to explicitly disclose “providing a secondary market for regulatory data and information obtained in one party's research and development whereby it can be utilized by another party in its territory”.

PR Newswire discloses, as best understood, licensing agreements providing a secondary market for regulatory data and information obtained in one party's research and development whereby it can be utilized by another party in its territory (abstract discloses Cortex pharmaceutical company licenses out rights in order to enable Servier to develop and commercialize Cortex's technology and research for their own research within Cortex's territory, where Servier's research is a secondary market and where Servier is using the data within Cortex's territory of Europe as suggested by the fact that another agreement allows joint research between the two companies in Europe as well).

Therefore, it would have been obvious to one of ordinary skill in the pertinent art at the time the invention was made to modify funding an intellectual property program of Nutter to include the secondary market as taught by PR Newswire in order to offset some of the clinical costs of research.

As per claim 2, Nutter further discloses, as best understood, “wherein said secondary market comprises granting certain territorial rights in a party's regulatory data and information for an amount compensation that may exceed a first party's cost of development” (§ 20 discloses obtaining funds from the sale of IP assets to apply to start up costs, where start up costs are costs of development).

As per claim 3, Nutter further discloses “wherein said compensation comprises royalty payments, the rate of which are proportional the commercial advantage conferred on the second party when the regulatory data and information is obtained” (§ 23 discloses royalty payments to the seller that is a periodic payment of a percentage of revenues, where a percentage is a proportion).

As per claim 4, Nutter discloses all of the elements of the claimed invention but fails to explicitly disclose “wherein said object of research and development is a pharmaceutical product”.

PR Newswire discloses licensing agreements where the object of the research and development is a pharmaceutical product (See abstract).

Therefore, it would have been obvious to one of ordinary skill in the pertinent art at the time the invention was made to modify funding an intellectual property licensing agreement program of Nutter to include the pharmaceutical product as taught by PR Newswire since such is a common object of research and development and licensing agreements.



As per claim 5, Nutter further discloses “wherein the territorial distribution of rights is provided by an exclusive territorial license” (¶ 23 discloses licensing rights to use the IP in a defined territory).

As per claim 6, Nutter further discloses “wherein the parties are independent entities” (Fig. 1 and ¶ 18 discloses independent entities).

As per claim 7, Nutter further discloses “at least three parties” (Fig. 1 and ¶ 18 discloses ovals that represent the entities involved, where there are 4 ovals that represent the different entities).

### ***Conclusion***

**12.** The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Martin (6,330,547) discloses a method and apparatus for establishing and enhancing the creditworthiness of intellectual. Panchal et al. (2003/0191654) discloses a patent product map. Silver (2003/0182166) discloses entrepreneurship evaluation methods and systems.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CANDICE D. CARTER whose telephone number is (571) 270-5105. The examiner can normally be reached on Monday thru Thursday 7:30am- 6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Weiss can be reached on (571) 272-6812. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/C. D. C./  
Examiner, Art Unit 3629

/John G. Weiss/  
Supervisory Patent Examiner, Art Unit 3629